Abstract: Yale Tobacco Center of Regulatory Science

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The Family Smoking Prevention and Tobacco Control Act, by empowering the FDA to regulate tobacco products, makes the crucial goal of reducing the appeal, addiction, and harmful effects of all tobacco products, including current and emerging modified risk tobacco products (MRTP's) more achievable. The overarching goal of the Yale Tobacco Center of Regulatory Science is to reduce addiction by developing a strong knowledge base on how flavors, including menthol, and sweeteners affect the initiation and development of addiction to current tobacco and modified risk tobacco products. Translational in nature, the four proposed studies bridge basic, clinical and population science. The Yale TCORS multidisciplinary team includes experts in chemosensory psychophysics (Barry Green), menthol and irritant receptor biology (Sven Jordt; Green), dopaminergic signaling in brain reward pathways (Nil Addy), nicotinic receptor biology (Marina Picciotto), adolescent tobacco use (Suchitra Krishnan-Sarin), human behavioral pharmacology (Mehmet Sofuoglu), tobacco addiction (Stephanie O'Malley/Benjamin Toll), clinical pharmacokinetics of drugs of abuse (Peter Jatlow), and health economics and decision making science (Jody Sindelar/Johanna Maclean). The proposed center addresses the following specific aims: 1) To galvanize research interest across disciplines and to provide the FDA with empirical evidence that might be used to develop policies to reduce addiction to tobacco products, 2) To conduct a series of programmatic studies to understand the role of flavors and sweeteners, including menthol, in modulating addictive potential of tobacco products, 3) To train a new generation of researchers who have experience in regulatory research and can synthesize evidence from multiple disciplines to generate tobacco policies, 4) To facilitate collaborations within and across centers through the use of standardized measures and methods, and development of collaborative research projects, 5) To provide a mechanism for rapid review and funding of pilot projects which support the goals of the Yale TCORS and other TCORS, and are also responsive to the ongoing regulatory needs of the FDA.